K011220

JUL 1 2002

510(k) Summary of Safety and Effectiveness

Trade Name	LeVeen™ Reflect™ Monopolar/Bipolar Needle Electrode
Common/Classification Name	Electrosurgical Electrode
Classification	Class II
Summary of Substantial Equivalence	The LeVeen™ Reflect™ Monopolar/Bipolar Needle Electrode is substantially equivalent to the previously cleared LeVeen™ Needle Electrode and the pre-amendment Greenwald Bipolar Needle Electrodes.
Device Description	The device consists of two, preshaped, multi-armed electrode arrays that are contained within an insulated delivery cannula. The arrays are attached to a handle mechanism that allows the arrays to be individually deployed out from the cannula into the targeted tissue. The device is connected to a RadioTherapeutics RF generator so that RF energy passes between the two arrays and heats the tissue surrounding the arrays and heats the tissue in between the arrays.
Intended Use	The LeVeen™ Reflect™ Monopolar/Bipolar Needle Electrode is intended to be used in conjunction with a RadioTherapeutics Corporation radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissue, including partial or complete ablation of nonresectable liver lesions.

RadioTherapeutics Corporation
1308 Borregas Avenue, Sunnyvale, CA 94089
(408) 745-3200 • Fax (408) 745-9848
April 18, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Corporation, Medi-Tech
NAMIC Technology Center
10 Glens Falls Technical Park, Dix Avenue
Glens Falls, New York 12801

Re: K011220
Trade Name: Leveen™ Reflect™ Monopolar/Bipolar Needle Electrode
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 24, 2002
Received: April 29, 2002

Dear Ms. Greenizen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: The LeVeen™ Reflect™ Monopolar/Bipolar Needle Electrode

Indications for Use: The LeVeen™ Reflect™ Monopolar/Bipolar Needle Electrode is intended to be used in conjunction with a RadioTherapeutics Corporation radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissue, including partial or complete ablation of nonresectable liver lesions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011220

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)